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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/796,239

03/09/2004

Fred T. Lee JR.

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BOYLE FREDRICKSON S.C.
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EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3735

NOTIFICATION DATE

DELIVERY MODE

07/10/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@boylefred.com

Office Action Summary	Application No. 10/796,239	Applicant(s) LEE ET AL.	
	Examiner david shay	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 28, 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 13 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13, and 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 28, 2008 has been entered.

With regard to the art rejection, applicant asserts that the examiner regards the trocar of Gough et al as a "primary antenna" and thus Gough et al do not teach the production of current flow between the two sets of extended antennae. The examiner must respectfully submit that applicant has misread the remarks of the previous office action. It appears, from the instant arguments, that applicant has attributed the remarks of the examiner which were drawn to the disclosure of Gough et al ('384) as pertaining to Gough et al ('143). However, a careful reading of these remarks, reproduced below for applicant's convenience, reveals that the disclosure of current flow from the pairs of axially separated antennae to the central shaft is a teaching contained in Gough et al ('384), and that the teachings of Gough et al ('143) are distinguished therefrom in this regard. See the remarks from the previous office action, below.

"With regard to the art rejection, applicant asserts that Gough et al ('143) does not teach an insulative member between the two sets of electrodes therein.

The examiner must respectfully disagree. Firstly, Gough et al ('143) do teach the use of an insulative sleeve, 18, as noted by applicant. Taking the totality of the disclosure of Gough et al ('143), along with the knowledge of one of ordinary skill in the art, the use of this sleeve at least along the length of the trocar at least between the two sets of antennas disclosed by Gough et al ('143), is fairly taught

therein. Firstly, it is noted that Gough et al ('143) was derived from a parent application, as a continuation in part, the parent application maturing in U. S. Patent No. 5,683,384, which specifically refers to the element 14 in the drawings thereof as a "primary antenna". Clearly the conversion of this element to a "trocar" in Gough et al ('143) is intended to convey that this element is can be used for purposes other than to send or receive energy. Secondly, column 5, lines 48-55, discusses that the insulating sleeve can be positioned around the trocar and can have one or more apertures, which permit the introduction of the antennas through the trocar and the insulating sleeve. Thirdly, in the discussion of Figure 4 at column 8, lines 1-4, Gough et al ('143) discuss a configuration wherein a lesion is produces "with a minimal central core that is not ablated." Thus clearly Gough et al ('143) were aware of the ability of the ability of the trocar to sink electrical current, if it was metal, and to provide an arrangement where an insulating sleeve could be deployed thereon to prevent the current from heating the tissue adjacent the trocar, should that be desirable."

With regard to the embodiment of Figure 8, of Gough et al ('143) applicant asserts that Gough et al ('143) "teaches that the trocar must be uninsulated". The examiner has been unable to locate any teaching whatsoever in Gough et al ('143) with regard to Figure 8, or any other Figure therein that asserts that the trocar "must" be uninsulated. Thus the examiner respectfully requests that applicant specifically point out the disclosure in Gough et al ('143) which is perceived to convey this requirement. To the contrary, the teachings found in Gough et al ('143) by the examiner state that an "insulation layer may be positioned in a surrounding relationship

around **at least** a portion of an exterior of the trocar.” (see column 3, lines 28-30, emphasis added). Thus, applicants arguments, predicated on the perceived teaching that the trocar “must” not be insulated must fail.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “support shaft having an outer surface and a distal tip, wherein the support shaft has an electrically insulated cover on the outer surface between a first and second locations, the cover extending to the distal tip of the support shaft; ... first and second wire electrode sets extensible radially from the shaft...” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

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should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because Figure 9 adds new matter, because the precise configurations of the kits now shown were not previously disclosed. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The amendment filed November 21, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: “support shaft having an outer surface and a distal tip, wherein the support shaft has an electrically insulated cover on the outer surface between a first and second locations, the cover extending to the distal tip of the support shaft; ... first and second wire electrode sets extensible radially from the shaft...”.

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 13, and 16-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on “support shaft having an outer surface and a distal tip, wherein the support shaft has an electrically insulated cover on the outer surface between a first and second locations, the cover extending to the distal tip of the support shaft; ... first and second wire electrode sets extensible radially from the shaft...”. The disclosure shows no embodiment where both sets of electrodes extend from the same shaft.

Claims 1-9, 13, and 16-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al ('143) in combination with Swanson et al. Gough et al ('143) teach a device as claimed except for the specific disclosure that the current is passed from one electrode set to the other and the specific frequencies claimed. Swanson et al teach using frequencies in the 1 KHz range, to which tissue has a high resistivity. It would have been obvious to the artisan or ordinary skill to employ the frequencies in the 1 KHz range, since these are frequencies to which tissue has a high resistivity, as taught by Swanson et al, and would thus produce more heating, and to configure the device to produce current flow in the axial direction when there are multiple electrodes, since this would ablate the tumor more quickly than the procedure involving rotation, discussed by Gough et al ('143), and to provide multiple sets of electrodes with the particular relative dimensions claimed, since this is not critical; is well within the skill of one having ordinary skill in the art; and provides no unexpected result, and to provide the insulating sleeve along at least the length of the trocar between the two sets of antenna, since this would prevent current from being grounded through the trocar, thus producing a device, kit, and method such as claimed.

Applicant's arguments filed April 28, 2008 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114.

See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3735